



Matthew Swainson
03/12/2010 04:21 PM

To Trevor Byrne
cc Mick O'Connor, Pamela Carter, Jane Cook, Larry Kelly, Virginia Deigan, Penny Lovell, Terry Lee

bcc

Subject Fw: TRIM: R10/410426 - Fw: RC-2010-RN-01196-3
Proposed product notification letter for cancelled thermographic cameras
[SEC=IN-CONFIDENCE]

IN-CONFIDENCE

Dear Trevor

I refer to your request for advice to Terry Lee below and attach a copy of the proposed notice with my amendments in track changes. The amendments I recommend are:

- set out a description of the device in full as it appears on the ARTG
- I note that you have decided not to carry out a recall of this device but instead are essentially warning those clinics/users in possession of the device that they cannot advertise its use. Therefore I think that it is important to set out clearly what the clinics cannot do and warn them that penalties may flow if they do not follow the requirements
- lastly I have made a small number of changes to ensure internal consistency in the notice



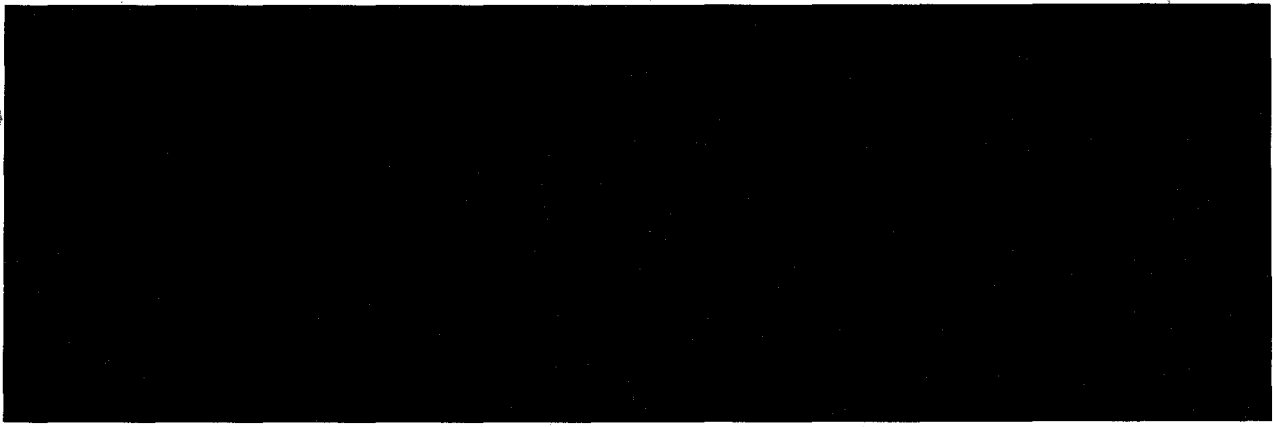
*Discussion with Pam Carter
work on for sponsor notification
7/12/10*

[redacted] - proposed sponsor notice - reviewed by OLS.DOCX

You have also asked about protocols and templates for publishing in the gazette. We do not have a template for s41KA notices however you may find the attached s30EA useful. Regarding protocols, once you have drafted the notice just provide a copy to OLS with instructions to publish in the gazette. We are happy to provide advice on any draft prior to publication.



section 30EA gazette notice.docx



Happy to discuss further if this would be helpful.

Matt Swainson
Legal Officer
Office of Legal Services
Therapeutic Goods Administration
(02) 6232 8982

[REDACTED] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [REDACTED]) that **Camera, thermagraphic (MED2000, MED2000 PRO, MED2000 IRIS)** with the ARTG number 143474 ("the Device") has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically we ask that you note the following:

(i) the Australian Register of Therapeutic Goods entry for the Device (ARTG number 143474) was cancelled from the Register-ARTG on 24 September 2010;

(ii) [REDACTED] requested the Secretary cancel the entry following a request for information and documents from the Therapeutic Goods Administration-TGA which included a request for evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 14 (which requires every medical device to have clinical evidence appropriate for the use and classification of the device) set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*; and

(iii) that you note there are advertising requirements for therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:

- a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the Register-ARTG (refer to section 42DL(1)(g) of the Act);
- that a therapeutic good cannot be advertised in a manner that is likely to be misleading or likely to lead to consumers inappropriately treating potentially serious diseases (see section 4(2) of the Code); and,
- that goods generally cannot be advertised in a manner that is likely to mislead or deceive (see section 53 of the TP Act).

Please be aware that penalties may apply for breaches of these requirements.

[REDACTED] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [REDACTED]) that Camera, thermographic (MED2000, MED2000 PRO, MED2000 IRIS) with the ARTG number 143474 ("the Device") has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically we ask that you note the following:

(i) the entry for the Device was cancelled from the ARTG on 24 September 2010;

(ii) [REDACTED] requested the Secretary cancel the entry following a request for information and documents from the TGA which included a request for evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 14 requires every medical device to have clinical evidence appropriate for the use and classification of the device; and

(iii) that there are advertising requirements for therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:

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